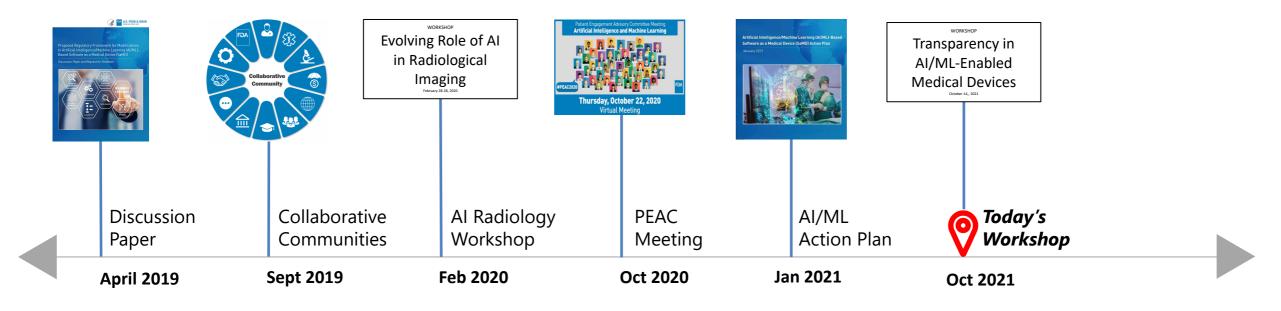


## Transparency of Artificial Intelligence/ Machine Learning (AI/ML)-Enabled Medical Devices: FDA Virtual Public Workshop

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## **Continuing Our Collaborative Approach**





#### Requesting Your Continued Input

Please submit your comments regarding the workshop to www.regulations.gov Docket No. FDA-2019-N-1185 by November 15, 2021

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### **Presentation Outline**



- Brief Overview of AI/ML-Enabled Devices
- Workshop Focus:
  - 1. What Does Transparency Mean?
  - 2. Why is Transparency so Important?
  - 3. How Can We Promote Transparency?

## AI/ML-Enabled Medical Devices



#### **Artificial Intelligence (AI):**

A branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviors such as learning, making decisions and making predictions.

#### **Machine Learning (ML):**

A subset of AI that allows computer algorithms to learn through data, without being explicitly programmed, to perform a task.

#### AI/ML-Enabled Medical Device:

A medical device that uses machine learning to achieve its intended medical purpose.

Descriptions adapted from IMDRF Artificial Intelligence Medical Devices Key Terms & Definitions Proposed document posted for public consultation Sept 2021 through Nov 29, 2021

http://www.imdrf.org/consultations/cons-aimd-mlmd-ktd.asp

## **Examples of AI/ML-Enabled Medical Devices**



**FDA News Release** 

FDA Authorizes Marketing of First Cardiac Ultrasound Software That Uses Artificial Intelligence to Guide User

February 7, 2020



Caption Guidance

**FDA News Release** 

FDA Authorizes Marketing of First Device that Uses Artificial Intelligence to Help Detect Potential Signs of Colon Cancer

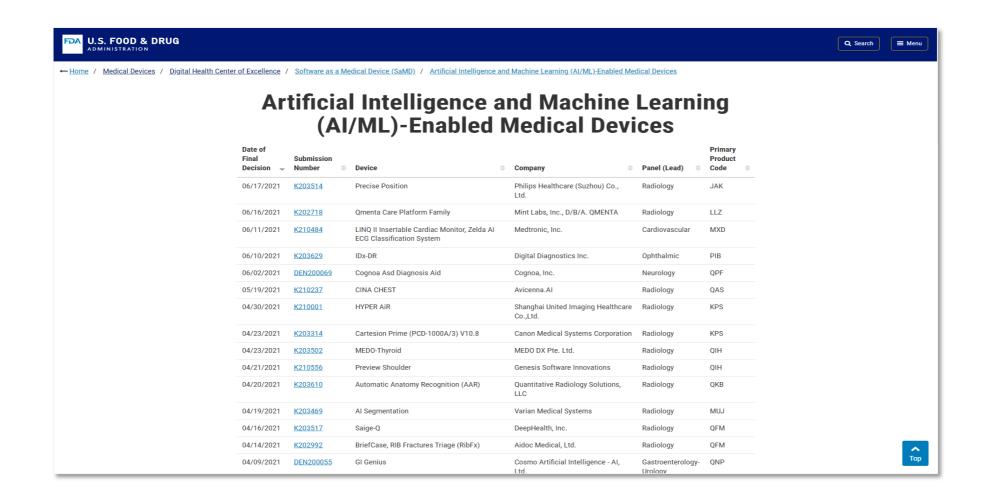
April 9, 2021



GI Genius

## FDA Resources on AI/ML-Enabled Medical Devices





# AI/ML-Enabled Medical Devices: Opportunities & Challenges



#### **OPPORTUNITIES**

- Significant positive impact on health care
  - Earlier disease detection
  - More accurate diagnosis
  - New insights into human physiology
  - Personalized diagnostics and therapeutics
- Applications across all medical fields
- Ability to learn, adapt, and improve performance

#### **CHALLENGES**

- Fit-for-purpose data sets for development and testing, including diversity
- Identification and minimization of bias
- Opacity of some algorithms
- Providing oversight for an adaptive system
- Ensuring transparency to users

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## **Working Definition of Transparency**





#### **TRANSPARENCY:**

Degree to which appropriate information about a device

including its intended use, development,
 performance, and, when available, logic –
 is clearly communicated to stakeholders

## Transparency is Fundamental to a Patient-Centered Approach



- 1. Allows patients, providers, and caregivers to make informed decisions
- 2. Supports proper use of a device
- 3. Promotes health equity
- 4. Facilitates evaluation and monitoring of device performance
- 5. Fosters trust and promotes adoption



## **Continuing to Improve Transparency**





- What are the needs of specific stakeholders?
- What is the appropriate information to communicate?
- What is the best way to communicate that information?
  - How can device labeling be improved?
  - How can other public-facing information be improved?
  - What else can be done to promote transparency?

**TRANSPARENCY:** Degree to which appropriate information about the device – *including its intended use, development, performance, and, when available, logic* – is clearly communicated to stakeholders

\*Working definition of Transparency, above, for purposes of this workshop adapted from ISO/IEC JTC1 SC42 WG1 25059 (draft)

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